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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,031	01/11/2002	Stephen F. Badylak	3220-69262	9094

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No. 10/044,031	Applicant(s) BADYLAK ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 17, 2009 has been entered.

Claim Objections

Claims 22, 23, 25, 26, 28, 29, and 31-34 are objected to because of the following informalities: the language "further comprising further comprising" is redundant. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not clear that the "endogenous" components have original support from the paragraph bridging pages 13 and 14. In

particular, it is not clear that the components mentioned in this paragraph, which the Applicant cited as support for the new claim language, are native or endogenous or whether they have been added to the matrix. For this reason, the Examiner asserts that the claim language now contains new matter. The Applicant is reminded that the addition of new matter at the time of the filing of a request for continued prosecution (RCE) is not permitted; see 37 CFR 1.114.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d) (1) and MPEP § 608.01(o). Correction of the following is required: as an alternative to the Section 112, first paragraph new matter rejection set forth above, the Examiner asserts that the claim terminology “endogenous”, **if it can be shown to have inherent original support**, does not have proper antecedent basis from the specification as required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Abraham et al (US 5,993,844). Abraham anticipates the claim language where

Abraham states that the final product is “endotoxin free” such that it is within the claimed range of less than 12 endotoxin units per gram; see column 8, line 55 to column 9, line 13 and column 4, line 49 to column 5, line 6.

The effective filing date of the present claims is August 22, 1997 because support for the range of “an endotoxin level of less than 12 endotoxin units per gram” is not present in either provisional application 60/024,693 or 60/024,542. Rather, the apparently narrower range of “essentially zero bioburden level” is supported in these applications.

In addition, present claims 4-6 do not have support from the provisional applications because there is no clear mention of the number of colony forming units thereof. Furthermore, claim 13 does not have clear support from the provisional applications; see page 2, line 19 of 60/024,693. Additionally, claims 9 and 15 have features that are not supported by the provisional applications.

With regard to claim 14, Applicants are directed to column 9, lines 13-24 of Abraham.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10, and 16-31 are rejected under 35 U.S.C. 102(e) as anticipated by

Abraham et al (US 5,993,844) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abraham et al (US 5,993,844) alone.

With regard to claims 21 and 22, the newly added term "endogenous" seems to suggest that the components are present in their native state within the matrix as opposed to being later added. However, it is not clear that "endogenous" components would be structurally different from the same components as present in the matrix of Abraham. For this reason, the Examiner asserts that the claimed structure is identical to that of Abraham because they are present in the tissue matrix in both the claimed prosthesis and in Abraham's prosthesis; see MPEP 2113 that is incorporated herein by reference due to the fact that "endogenous" suggests process of making difference rather than a clear structural difference. The Applicants are directed to the paragraph bridging columns 10 and 11 where it discloses that glycoproteins, glycosaminoglycans, and proteoglycans can be added back into the tissue matrix.

Alternatively, if there is a difference implied by the use of "endogenous", the Examiner asserts that it is slight such that the claimed invention is clearly obvious in view of Abraham alone. Furthermore, the endogenous components are considered at least clearly obvious over Abraham alone because Abraham teaches adding the same component(s) back into the matrix.

Regarding claims 7-10, 16-20, and 23-31, Abraham reasonably discloses the claimed invention as explained *supra* but fails to clearly disclose the product-by-process steps recited in the claims; see MPEP 2113 that is incorporated herein by reference. However, the claimed product appears to be identical to the product disclosed by

Abraham such that the claimed invention is considered anticipated thereby.

Alternatively, since the present claims contain product-by-process limitations, it is not explicitly clear that the product resulting from these process steps results in a product that is identical or substantially identical to that of Abraham. However, even if the process steps result in a different product from that of Abraham, the Examiner asserts that the difference is slight such that the claimed invention would have been considered at least obvious in view of Abraham alone.

With regard to claim 16, the tela submucosa claimed is inherently present in the tissue of Abraham since the same tissue as claimed is purified by Abraham.

Claims 1-3, 7-11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yannas et al (US 4,060,081) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yannas et al (US 4,060,081) alone. Yannas anticipates the claim language where purified collagen is used to make the graft so it is indistinguishable from collagen of other sources in that all the other source components have been removed. The purified structure is inherently free of endotoxins because it is all endotoxins have been removed; see the abstract and example 1 on columns 14 and 15; see MPEP 2113 that is incorporated herein by reference thereto.

Alternatively, if there is a difference in the collagen due to the source utilized to make it that difference is so slight that it would have been considered *prima facie* obvious to an ordinary artisan viewing Yannas purified collagen.

Claims 12, 13, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al (US 5,993,844) alone. Abraham meets the claim

Art Unit: 3774

language as explained in the rejection of base claim 1, but fails to disclose a tubular, tendon, or ligament form of the implant matrix. However, the Examiner asserts that a tubular, tendon, or ligament form of the Abraham implant matrix would have been considered obvious to an ordinary artisan since any body part (see column 4, lines 31-48) including tubular or ligament tissues (arteries, veins, intestines, heart valves, dermis, and ligaments; see column 8, lines 55-57) can be used to replace any portion of the patient's body in need thereof.

Claim 15 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al (US 5,993,844) in view of Braun (US 3,562,820). Abraham meets the claim language as explained in the rejection of base claim 1 but fails to disclose strips of submucosa fused together as claim. However, Braun teaches that it was known to use strips of tissue fused together to form implants; see the abstract and the figures. Therefore, it is the Examiner's position that it would have been obvious to fuse two or more strips of the Abraham tissue matrix together in order to make a stronger or thicker tissue implant to adapt it to the implant site as implicitly suggested by Braun.

Interference Sought

It is noted that the Applicants are seeking to provoke an interference with another assignee of the same subject matter. The request for interference filed March 14, 2008 is acknowledged. However, examination of this application has not been completed as required by 37 CFR 41.102(a). Consideration of a potential interference is premature. See MPEP § 2303.

Response to Arguments

Applicant's arguments filed July 17, 2009 have been fully considered but they are not persuasive.

The Applicants argue that the language "collagen-based matrix structure" is specially defined in the specification as "one or more naturally occurring components including glycoproteins, glycosaminoglycans, and proteoglycans and/or growth factors" by referring to page 14, lines 1-2 of the specification. However, upon review of the entire paragraph bridging pages 13 and 14, it is clear that no special definition is being invoked, and that the definition is clearly an exemplification.

An inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.' see *Teleflex, Inc. v. Ficosa No. Am. Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002). In this case, the definition is clearly one of exemplification and is not clear and deliberate as required. This is due to fact that specification states that "**preferred** matrices of the invention will contain beneficial components with which matrices naturally occur, including **for example** one or more glycosaminoglycans, glycoproteins, proteoglycans, and/or growth factors" (emphasis added herein). Clearly, the collagen matrix need not contain these components in order to be considered a collagen matrix within the scope of this claim term.

With regard to the argument that the effective filing date of claim 3 is now before the effective date of Abraham, the Examiner notes that claim 3 is dependent upon claim

1 that contains subject matter added August 22, 1997. For this reason, claim 3 also has an effective filing date of August 22, 1997. Nonetheless, the Examiner has added a rejection under 102(b)/103(a) that demonstrates that the invention set forth in claim 3 was known at the time the invention was made.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774